

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 56-63, 65-73, 76-77, and 80-81 are pending in the present application. Claims 56 and 73 have been amended to a preparation and composition, respectively. In addition, claim 73 has also been amended to further a ratio for long chain polyunsaturated fatty acids that are present in the composition. Claims 80-81 have been added. Support for the newly claims and amendments to the claims may be found in the present specification at page 7, lines 1-10 and page 11, line 18 of the present specification.

In the outstanding Official Action, claims 56-63, 65-72, 76, and 77 were rejected under 35 USC §112, first paragraph, for allegedly not satisfying the enablement requirement. Applicants believe the present amendment obviates this rejection.

While applicants do not disclaim any potential applications or uses for the claimed preparation and claimed composition, independent claims 56 and 73 have been respectively amended to recite a preparation and a composition that are not limited by a recited use. Thus, the objectionable language identified by the Office Action is no longer recited.

As the Examiner is aware, when a compound or composition claim is not limited by a recited use, any enabled

use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use. If multiple uses for claimed compounds or compositions are disclosed in the application, then an enablement rejection must include an explanation, sufficiently supported by the evidence, why the specification fails to enable each disclosed use. In other words, if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention (see MPEP § 2164.01(c)). As a result, applicants believe that the present amendment obviates this rejection.

Claims 56 and 76 were rejected under 35 USC §112, second paragraph, for allegedly being indefinite. Applicants believe the present amendment obviates this rejection.

Claim 56 was rejected because it was allegedly unclear as to whether the claimed preparation contained DHA. However, applicants believe that claim 56 has been amended in a manner so that the claim is definite to one skilled in the art.

Claim 76 was rejected because it was allegedly unclear as to what recitations were a part of the claim in light of the use of terms "and/or". However, this terminology has been deleted from the claim.

Accordingly, applicants believe that the claimed invention is definite to one skilled in the art.

Claims 56-58 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN 4,810,497, DELLA VALLE et al. 4,595,680 and FUGH-BERMAN et al. This rejection is respectfully traversed.

Applicants maintain that HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al. fail to render obvious the claimed invention for the same reasons as those set forth in the amendment file on May 17, 2005. Nevertheless, in the interest of advancing prosecution, applicants submit herewith a declaration by M. C. de Wilde. It is believed that that the present declaration provides further evidence that the claimed invention is not obvious in view of the teachings of HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al.

In the declaration, three diet compositions (diet composition A, B, and C) were prepared and tested on aged rats. Diet A serves as a control diet. Diet B is a composition prepared on the basis of the teachings of Horrobin (US 4595680), della Valle et al. (US 4810497), and Fugh-Berman et al (1999). This diet comprises the fatty acids levels of DHA, EPA and GLA plus citrate as found in Horrobin (e.g., example 2, no. 5), a ratio of the phospholipids PS (75%) and PC (25%) as taught in della Valle (see example 5a), and the presence of B-vitamins and folate as disclosed by Fugh-Berman. Diet C is a composition providing DHA and EPA plus phospholipids plus B-vitamins according to the claimed invention.

Aging is believed to be the predominant cause of cerebrovascular damage and resulting memory decline. These deficits were exemplified in rats by using a memory function assessment task like the Radial Arm Water Maze (RAWM).

The declaration shows that the diet composition exemplified by the claimed invention (Diet C) unexpectedly and significantly improved memory performance of aged rats in the test. The memory performance of rats fed the diet composition formulated on the basis of the teachings of HORROBIN, DELLA VALLE et al, FUGH-BERMAN et al. (Diet B) and the control diet (Diet A) was significantly less than that of rats fed the diet composition in accordance with the claimed invention. In view of the unexpected results set forth in the declaration, it is believed that HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al. fail to render obvious the claimed invention.

Indeed, by following the plain teachings of the publications, it would be unexpected that the claimed combination of components and amounts recited in the preparation of claim 56 would result in the desired result. One skilled in the art would lack the motivation to further modify the publications in any manner so as to obtain the claimed preparation.

Furthermore, the Examiner's attention is respectfully directed to claims 73, which recites a composition comprising at least one long chain polyunsaturated fatty acid fraction selected from the group consisting of eicosapentaenoic acid (EPA),

docosahexaenoic acid (DHA), dihomogammalinolenic acid (DHGLA), and arachidonic acid (AA); and at least one long chain polyunsaturated fatty acid fraction selected from the group consisting of linoleic acid and  $\alpha$ -linoleic acid; at least two different phospholipids selected from the group consisting of phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and least one factor in methionine metabolism, selected from the group consisting of folic acid, vitamin B12, vitamin B6, magnesium and zinc, *wherein the ratio of the total amount of EPA + DHA + DHGLA + AA to the total amount of linoleic acid and  $\alpha$ -linoleic acid is larger than 0.1:1.*

The diet compositions formulated on the basis of the teachings of HORROBIN, DELLA VALLE et al, FUGH-BERMAN et al. (Diet B) and the control diet (Diet A) fall plainly outside the scope of the claimed ratio relating to the total amount of EPA + DHA + DHGLA + AA to the total amount of linoleic acid and  $\alpha$ -linoleic acid. This also stands true for the claimed amounts recited in claims 61, 66, and 76 along with new claims 80 and 81. There is simply no recognition or expectation that the a combination of HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al. would provide the unexpected and improved memory performance as exhibited by the rats that were fed the claimed preparation/compositon.

As a result, applicants believe that the proposed combination of HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al. fails to teach the claimed invention.

Claims 56-58, 76 and 77 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, DELLA VALLE et al, FUGH-BERMAN et al. and TAIYO FISHERY CO., LTD. This rejection is respectfully traversed.

Applicants respectfully submit that the TAIYO FISHERY CO., LTD. publication fails to remedy the deficiencies of HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al. Indeed, the TAIYO FISHERY CO., LTD. publication does not even discuss long-chain fatty acids.

Thus, applicants believe that the proposed combination fails to render obvious the claimed invention.

Claims 63 was rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al. and YU et al. 5,177,082. This rejection is respectfully traversed.

Applicants note that YU et al. are silent as to long-chain fatty acids. As a result, applicants believe that YU et al. fail to remedy the deficiencies of the above-identified publications.

As a result, applicants believe that the combination of HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al. and YU et al. does not render obvious the claimed invention.

Claims 64-65 were rejected under 35 USC 103(a) as allegedly being unpatentable over HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al. and SMITH et al. 6,008,221. This rejection is respectfully traversed.

SMITH et al. do not remedy the deficiencies of HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al for reference purposes. SMITH et al. neither disclose nor suggest the amounts and ratios as set forth in the claimed invention.

Thus, applicants believe that the proposed combination fails to render obvious claims 64-65.

Claims 65-66 were rejected under 35 USC 103(a) as allegedly being unpatentable over HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al. and HUTTERER 4,837,219. This rejection is respectfully traversed.

However, HUTTERER fails to teach the administration of long-chain fatty acids as set forth in the claimed invention for treating Alzheimer's disease, any of the claimed amounts and ratios.

Thus, applicants believe that HUTTERER does not remedy the deficiencies of HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al. for reference purposes.

Accordingly, applicants respectfully request that the rejection be withdrawn.

Claims 71 was rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, DELLA VALLE et al.,

FUGH-BERMAN et al., SMITH et al., HUTTERER and GLICK 5,004,615.  
This rejection is respectfully traversed.

GLICK is concerned with the administration of dietary supplements for preventing and controlling dementia and memory loss. However, GLICK does not direct one skilled in the art to administer long-chain fatty acids.

As a result, applicants believe that the proposed combination fails to render obvious the claimed invention.

Claims 67 and 68 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al. and RABIEN (DE 4309217). This rejection is respectfully traversed.

RABIEN teaches a composition comprising alpha lipoic, panthothenic acid and vitamin E for treating Alzheimer's disease. However, RABIEN does not teach the administration of long-chain fatty acids. Additionally, RABIEN provides no suggestion to one skilled in the art to combine and modify the proposed combination of publication in a manner so as to obtain the claimed amounts or ratios.

As a result, applicants request that the rejection be withdrawn.

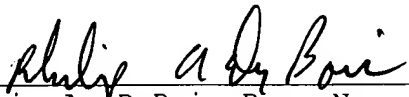
In view of the present amendment and the foregoing remarks, therefore, it is believed that this application is now in condition for allowance. Allowance and passage to issue on that basis are accordingly respectfully requested.



The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item:

- Declaration under Rule 132 by M. C. de Wilde